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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,774	10/29/2001	Alessandra D'Azzo	2427/1F509-US1	9922

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,774	D'AZZO ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *1-8, 18, 22-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-17 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Applicants' arguments filed April 30, 2004, have been fully considered but they are not persuasive. Applicants' position regarding the election of one sequence is that the elected SEQ ID NO: 1 is a species which reads on human Ozz nucleic acid of SEQ ID NO:3. The Examiner respectfully disagrees for reasons of record as supplemented below.

This is not found persuasive because each of the sequences are different in composition and nucleotide sequence which encode different proteins that have different amino acid sequences and compositions. SEQ ID NO: 1 and SEQ ID NO: 3 encompass patentably distinct sequences from different biological sources that encode different proteins and require different searches that are not co-extensive. The requirement has been made FINAL in the previous Office Action and is still deemed proper.

2. Claims 9-17 and 19-21 and SEQ ID NOS: 1 and 2 are under consideration in this Office Action.

Claim Objections

3. Claims 12, 20, and 21 stand objected to because of the claims recited non-elected subject matter of the nucleotide sequence of SEQ ID NO: 3 . Applicants are required to cancel the claims or rewrite the claims to recite the elected sequence of SEQ ID NO: 1 and polynucleotide encoding SEQ ID NO: 2.

Claim Rejections - 35 U.S.C. § 101

4. Claims 9-17 and 19-21 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants' arguments filed April 30, 2004, have been fully considered but they are not persuasive. Applicants' position is that the Ozz nucleic acids is useful for making Ozz protein, which in turn is useful for detection of conditions associated with muscle damage; Ozz nucleic acids are used as a research agent for identifying drugs that treat myogenesis disorders; and Ozz protein accumulation in galactosialidosis can be used to diagnose diseases. The Examiner respectfully disagrees for reasons of record as supplemented below.

The assertion that the claimed Ozz nucleic acids can be useful to recombinantly make Ozz protein or as a research agent for identifying drugs are generic utilities which can be applicable to any nucleic acid, and thus is not a specific utility. The specification does not teach how any drug which has any effect on the Ozz protein can be useful to treat any myogenesis disorder.

The assertion that Ozz protein accumulation in galactosialidosis can be used to diagnose diseases is not substantial since further experimentation is required to correlate any overexpression and localization of the Ozz protein in galactosialidosis to any heart or skeletal muscle myopathies. Substantial utility is one that provides a specific benefit in currently available form at the time of filing of the invention. However, the main utility of the nucleic acid and protein is to carry out further research to identify the biological function and possible diseases associated with the protein.

The specification does not disclose the specific function of the protein of SEQ ID NO: 2 or any activity assays to demonstrate that the protein has any biological activity. As stated in the previous Office Action, the specification shows sequence alignments between the claimed invention and Drosophila melanogaster and D. virilis neuralized protein. However, homology is not a disclosure of how to use the protein or polynucleotide encoding the protein of SEQ ID NO: 2. The specification does not explicitly state that homology to a reference polypeptide known in the prior art is a disclosure that the claimed polypeptide has the properties and biological function of the reference polypeptide relied upon.

Utilities that require or constitute carrying out further research to identify or reasonably confirm a specific use are not substantial utility and do not provide a specific benefit. Thus, the claimed invention has no specific or substantial asserted utility, and thus has no well- established utility.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. Claims 9-17 and 19-21 stand rejected under 35 U.S.C. 112, first paragraph. Since the claimed invention is not supported by either a specific or substantial asserted utility or well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

6. Claims 20 and 21 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed April 30, 2004, have been fully considered but they are not persuasive. Applicants' position is that the claims are amended to recite 10 consecutive nucleotides and that the specification discloses oligonucleotide primers and probes. Applicants thus conclude that the there is sufficient disclosure of physical characteristics and functional characteristics. The Examiner respectfully disagrees for reasons of record as supplemented below.

Claims 20 and 21 are genus claims that are directed toward all possible nucleic acids comprising any 10 consecutive nucleotides of SEQ ID NO: 1. The scope of the claim includes many polynucleotides with widely differing structural, chemical, biological, and physical characteristics. Furthermore, the genus is highly variable because a significant number of structural differences between genus members is permitted.

The disclosed polynucleotide consisting of a nucleotide sequence of SEQ ID NO: 1 and a polynucleotide encoding a polypeptide consisting of an amino acid sequence of SEQ ID NO: 2 is not representative of the entire claimed genus since member of the genus include polynucleotides that have structural and biological properties that are different from the disclosed Ozz nucleic acid of SEQ ID NO: 1 which encodes the Ozz protein of SEQ ID NO: 2. The specification does not disclose other representative nucleic acids of the claimed genus. Furthermore, there is no recitation of any particular structure to function/activity relationship in claims 20 and 21 that clarify what common attributes are shared by members of the claimed genus.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Amending the claims to recite only an isolated nucleic acid consisting of at least 10 consecutive nucleotides of SEQ ID NO: 1 which function as probes or primers may over come the rejection.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

7. Claim 20 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants' arguments filed April 30, 2004, have been fully considered but they are not persuasive. Applicants' position is that "high stringency" is defined in the specification and that the PPCA exon Ia is well known. The Examiner respectfully disagrees for reasons of record as supplemented below.

MPEP §2111 states that claims must be given their broadest reasonable interpretation

consistent with the specification and that the claims of the instant invention must be read in light of the specification to thereby interpret limitations explicitly recited in the claims. Thus, limitations of the specification cannot be read into the claims to narrow the scope of the claims by implicitly adding disclosed limitations which are not recited in the claims.

Hence, claim 20 is vague and indefinite because the specific stringent hybridization conditions have not been recited and that the specific nucleotide sequence/structure of the "PPCA exon Ia" has not been recited.

Amending the claim to recite the specific hybridization conditions and the specific SEQ ID NO corresponding to the nucleotide sequence of the "PPCA exon Ia" may overcome the rejection.

Claim Rejections - 35 U.S.C. § 102

8. Claims 9-11 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. (Oncogene. 1998 Feb 26;16(8):1009-19). The teachings of Nakamura et al. have been stated in the previous Office Action.

Applicants' arguments filed April 30, 2004, have been fully considered but they are not persuasive. Applicants' position is that the Ozz protein is disclosed as having a specific tissue expression and that the Ozz protein is present in muscle and not nervous tissue. Applicants thus conclude that the Nakamura et al. reference does not anticipate claims 9-11. The Examiner respectfully disagrees for reasons of record as supplemented below.

MPEP §2111 states that claims must be given their broadest reasonable interpretation consistent with the specification and that the claims of the instant invention must be read in light of the specification to thereby interpret limitations explicitly recited in the claims. Thus, limitations of the specification cannot be read into the claims to narrow the scope of the claims by implicitly adding disclosed limitations which are not recited in the claims.

In view of MPEP §2111 and as stated in the previous Office Action, the claims are interpreted as encompassing any nucleic acid encoding any protein involved in development and function of muscle with homology with Drosophila *neu*, and is not limited to expression in any specific muscle and nervous tissue and is not limited to any specific biological function in the development and function of muscle.

Since the claims do not recite any tissue specific expression limitation and any specific biological function, then the Nakamura et al. reference anticipates the claimed invention, where Nakamura et al. teach a cDNA encoding a human homolog of the Drosophila neuralized gene.

Amending the claims to recite the specific SEQ ID NO may overcome the rejection.

9. The rejection of claims 13 under 35 U.S.C. 102(b) as being anticipated by Prinos et al. has been withdrawn in view of the addition of the limitation of a molecular weight of 30 kDa in the present **AMENDMENT** dated April 30, 2004. Prinos et al. do not teach a mouse nucleic acid encoding an Ozz protein with a molecular weight of 30 kDa.

10. Claim 20 stands rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (Accession AA800025). The teachings of Lee et al. have been stated in the previous Office Action.

Applicants' arguments filed April 30, 2004, have been fully considered but they are not persuasive. Applicants' position is that the specification defines the "stringent conditions" for which the nucleic acid taught by Lee et al. cannot hybridize to since nucleotides having a high degree of sequence similarity will hybridize . The Examiner respectfully disagrees for reasons of record as supplemented below.

MPEP §2111 states that claims must be given their broadest reasonable interpretation consistent with the specification and that the claims of the instant invention must be read in light of the specification to thereby interpret limitations explicitly recited in the claims. Thus, limitations of the specification cannot be read into the claims to narrow the scope of the claims by implicitly adding disclosed limitations which are not recited in the claims.

Hence, since no specific hybridization conditions have been recited, then the nucleic acid taught by Lee et al. is expected to hybridize to SEQ ID NO: 1 because there are regions that have high similarity to SEQ ID NO: 1. Furthermore, in the alignment between the nucleic acid taught by Lee et al. and SEQ ID NO: 1 (attached to the previous Office Action), there are several regions that contain 10 contiguous nucleotides that are identical to SEQ ID NO: 1. See the alignment between positions 607 and 846 of the top nucleotide sequence which represents SEQ ID NO: 1.

Conclusion

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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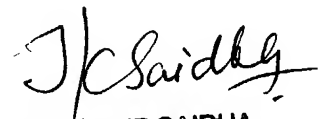

TEKCHAND SAIDHA
PRIMARY EXAMINER